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The outcomes of transcatheter aortic valve implantation with Edwards SAPIEN or CoreValve devices: Single-center experience in Turkey

Edwards SAPIEN ve CoreValve cihazlar ile transkateter aort kapak implantasyonu sonuçları: Türkiye'den tek merkezli deneyim

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Background: This study aims to evaluate early- and mid-term outcomes of transcatheter aortic valve implantation.

Methods: Between October 2010 and February 2012, 35 patients (16 males, 19 females; mean age 77.4±6.9 years; range 58 to 91 years) who were at high risk for surgery (EuroSCORE 26.0±9.9) and underwent transcatheter aortic valve implantation in our clinic were included. Edwards SAPIEN (n=27) and CoreValve prostheses (n=8) were implanted by transfemoral (n=33), transapical (n=1), and subclavian (n=1) approaches. The mean preoperative echocardiographic valve area was 0.6±0.1 cm^2, while the mean transvalvular gradient was 53.3±8.0 mmHg.

Results: The procedural success rate was 97%. Following the procedure, the mean transvalvular gradient decreased to 9.8±2.7 mmHg, whereas the average aortic valve area increased to 1.9±0.2 cm^2. The mean NYHA functional capacity reduced from 3.5±0.5 before the procedure to 1.4±0.6 at three months during follow-up (p<0.001). A significant increase in the mean left ventricular ejection fraction (LVEF) was observed at one month (52.5±10.4% versus 50.1±11.4%, p<0.001). Permanent pacemaker implantation was required in four patients (3 CoreValve, 1 Edwards SAPIEN). Four patients (%11.4) died within the first 30 days of follow-up. Nine patients died during a mean of nine months (range 0-17 months), including procedural mortality.

Conclusion: Our single-center procedural success rate and early- and mid-term follow-up outcomes are promising for this patient group, showing consistency with the other studies in the world.

Key words: Aortic valve stenosis; bioprosthetic valve; transcatheter aortic valve implantation.

Amaç: Bu çalışmada transkateter aort kapak implantasyonunun erken ve orta dönem sonuçları değerlendirildi.

Çalışma planı: Ekim 2010 - Şubat 2012 tarihleri arasında kliniğimizde transkateter aort kapak implantasyonu yapılan, cerrahi riski yüksek (EuroSCORE 26.0±9.9) 35 hasta (16 erkek, 19 kadın; ort. yaş 77.4±6.9 yıl; dağılım 58-91 yıl) çalışmaya dahil edildi. Edwards SAPIEN (n=27) ve CoreValve protezler (n=8) transfemoral (n=33), transapikal (n=1), subklavian (n=1) yaklaşım ile yerleştirildi. Hastaların işlem öncesi ekokardiyografik ortalama kapak alanı 0.6±0.1 cm^2, ortalama transvalvüler gradiyent 53.3±8.0 mmHg idi.

Bulgular: İşlemin başarı oranı %97 idi. İşlem sonrasında ortalama transvalvüler gradiyent 9.8±2.7 mmHg'ye gerilerken (p<0.001), kapak alanı 1.9±0.2 cm^2'ye yükseldi (p<0.001). Hastalarda işlem öncesi 3.5±0.5 olan NYHA fonksiyonel kapasite işlem sonrası üç aylık takipte 1.4±0.6'ya geriledi (p<0.001). Hastaların sol ventrikül ejeksiyon fraksiyonlarında işlem öncesine göre birinci ayda anlamlı derecede artma saptandı (%50.1±11.4'e kıyasla %52.5±10.4, p<0.001). İşlem sonrası dört hastada kalıcı pil gereksinimi oldu (3 CoreValve, 1 Edwards SAPIEN). İlk 30 günlük takipte dört ölüm olayı görüldü (%11.4). İşleme bağlı mortalite dahil ortalama 9 aylık takip süresince (dağılım 0-17 ay) dokuz hasta kaybedildi.

Sonuç: Tek merkezli olarak işlem başarımız ve erken ve orta dönem sonuçlarımız, dünyadaki diğer çalışmalarla paralel olarak bu hasta grubu için ümit vericidir.

Anahtar sözcükler: Aort kapak darlığı; biyoprotez kapak; transkateter aort kapak implantasyonu.

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As life expectancy increases, so does the aging population and the number of patients with aortic valve disease. Once the symptoms appear (e.g. angina, syncope, heart failure), the average survival may be as short as two to three years with a high risk of sudden death unless patients undergo surgical aortic valve replacement.[1] Surgical replacement of the aortic valve reduces the symptoms and improves the survival rate for patients with aortic stenosis, and in the absence of serious coexisting conditions, the procedure is associated with low operative mortality.[2] However, in clinical practice, at least 30% of patients with severe aortic stenosis do not undergo surgery for aortic valve replacement mainly because of the presence of severe comorbidities and associated surgical risk.[3]

Once aortic stenosis becomes symptomatic, medical treatment does not change the course of the rapidly worsening prognosis, with first- and five-year survival rates of 60% and 32%, respectively.[4] Since the mid- and long-term results are not favorable with balloon valvuloplasty, it is only used for palliative purposes.[5] Thus, the development of less invasive aortic valve replacement strategies has received considerable attention for these patients. Transcatheter aortic valve implantation (TAVI) has emerged as an alternative to surgical aortic valve replacement for patients with severe symptomatic aortic stenosis since they are considered to be at a very high or prohibitive operative risk.[6]

This study aimed to present the short- and mid-term results of 35 patients undergoing TAVI, together with complications encountered during the procedure.

PATIENTS AND METHODS

The study included 35 consecutive patients (16 males, 19 females; mean age 77.4±6.9 years; range 58 to 91 years) who underwent TAVI between October 2010 and February 2012. Twenty-seven patients received the balloon-expandable Edwards SAPIEN (Edwards Lifesciences, Irvine, California, CA) while eight patients received the self-expanding CoreValve (Medtronic, Minneapolis, MN) prostheses by the transfemoral (TF) (n=33), transapical (TA) (n=1), and subclavian (n=1) approaches.

All patients had severe aortic stenosis and NYHA class III or IV symptoms and were at high risk for surgery due to comorbidities, including chronic obstructive pulmonary disease (COPD), pulmonary hypertension, peripheral artery disease, hemodynamic instability, low ejection fraction, and coexistent diseases. The decision for TAVI was rendered by a consensus at a meeting of the heart team, and preoperative risk was assessed on the basis of the European System for Cardiac Operative Risk Evaluation (EuroSCORE) or the Society of Thoracic Surgeons (STS) risk calculator systems.[7,8] In the absence of other contraindications to surgical valve replacement, high-risk status was defined as a logistic EuroSCORE >20% or an STS score >10%.

The exclusion criteria were as follows: a narrow or too wide annulus of the aortic valve (≤18 mm or ≥27 mm) on echocardiography, an aortic valve area of more than 0.8 cm^2, a short distance between the main coronary artery and the aortic valve (for Edwards SAPIEN valve <8 mm, for CoreValve <14 mm), an aortic outflow tract obstruction associated with a severely sigmoid septum, severe left ventricular systolic dysfunction (LVEF <20%), acute myocardial infarction, severe coronary artery disease requiring revascularization, active infection, and a life expectancy of less than 12 months due to non-cardiac causes.

The severity of aortic stenosis, the aortic valve structure, and the aortic root were evaluated by transthoracic echocardiography (TTE) and transeosophageal echocardiography (TEE). Multislice computed tomography (CT) and angiography were performed for the assessment of aortic root-arch calcification, diameters of the femoral and iliac arteries, and calcifications and tortuocities. Coronary arteries were evaluated before the procedure through standard coronary angiography. Multislice CT and TEE were performed for all patients. As multislice CT is likely to overestimate annulus measurements, TEE is now the standard for the final determination of annular dimensions. The patients were assigned either the TF, TA, or subclavian approach depending on the condition and size of the iliofemoral arteries as well as the degree of calcification. New-generation valves and delivery systems were used, and patients were considered to be eligible for the TF approach if their iliac and femoral arteries were at least 6 mm in diameter. In one patient, the CoreValve device was implanted through the left subclavian arterial access, and another patient with peripheral artery occlusive disease underwent TA placement of the Edwards SAPIEN valve.

Despite having peripheral arterial disease, two patients underwent a TF procedure. One patient suffering from bilateral iliac artery occlusive disease underwent TF TAVI and a peripheral percutaneous approach simultaneously. In another patient with an aortoiliac graft for peripheral arterial occlusive disease, the left femoral artery and the left aortoiliac graft were used for access. One patient with Heyde's syndrome (gastrointestinal bleeding due to angiodysplasia and aortic stenosis) also had a successful TAVI procedure. Percutaneous coronary intervention (PCI) for coronary

Table 1. Important points for selection of the valve type in our patients

Annulus size	18-19 mm for Edwards SAPIEN and 26-27 mm for CoreValve
Calcification of valve	Edwards SAPIEN valve should be selected for high radial force
Horizontal aortic root	Intraannular valve can be placed easier
Ascending aorta	CoreValve is contraindicated in diameters above 43 mm
Route of access	Transapical approach for Edwards SAPIEN and subclavian approach for CoreValve can be used
Coronary artery disease	If percutaneous coronary intervention is anticipated in the future, the Edwards SAPIEN valve should be preferred. CoreValve with the left subclavian approach is very risky in patients with a patent LIMA
Poor left ventricular function	Edwards SAPIEN valve carries a high risk for LVOT obstruction during very fast pacing

revascularization was performed on seven patients two-three weeks prior to the TAVI procedure and on three patients at the same time as the TAVI.

In our institution, the first TAVI procedure was accomplished using the CoreValve, the first time this device had been used in our country. Today, the TAVI procedure is successfully performed with appropriate indications. Table 1 summarizes the relevant aspects that were taken into consideration in deciding which valve type to use in our patients. All the patients were informed of this prior to the operation, and their informed consent was obtained.

Assessment of cardiovascular events. All procedural and in-hospital events were recorded. Procedural success was defined as the expansion of the bioprosthetic valve in the proper position and its functioning with a tolerable degree of aortic insufficiency. After discharge, the patients underwent routine screening and echocardiography at one, three, six, nine, and 12 months. In some patients living in other cities, follow-up data was obtained via telephone conversations. The primary end point was cardiac death. A death was deemed to be of cardiac origin when the primary cause was due to myocardial infarction, arrhythmia, refractory congestive heart failure, or sudden death. Deaths associated with non-cardiac causes were also recorded.

Procedure

The TAVI procedure was performed in a sterile environment (catheterization laboratory) under general or local anesthesia. The femoral artery, with its greater diameter and less tortuosity, was selected. Two sheaths were placed in the contralateral femoral artery and femoral vein for placement of a pigtail catheter in the aorta and a pacemaker lead in the right ventricle, respectively. For the proper procedure, the balloon was predilated after passing the native valve with a straight-tip guide wire and an Amplatz left guide catheter. During balloon predilatation, ventricular tachycardia was induced by rapid ventricular pacing, providing an optimal reduction in cardiac output by creating transient cardiac standstill. This was usually achieved at a heart rate of 200 bpm. The CoreValve or Edwards SAPIEN valves were then passed through the delivery systems and expanded at the level of the native valve. Rapid ventricular pacing was repeated at that stage in patients in whom an Edwards SAPIEN valve was used. Since the CoreValve device is self-expanding, there was no need to repeat rapid ventricular pacing at that stage. The aortic root and peripheral arteries were evaluated after the intervention by contrast injection in the aortic root and by peripheral angiography. The stages of valve placement for the Edwards SAPIEN and CoreValve devices are illustrated in Figures 1 and 2, respectively.

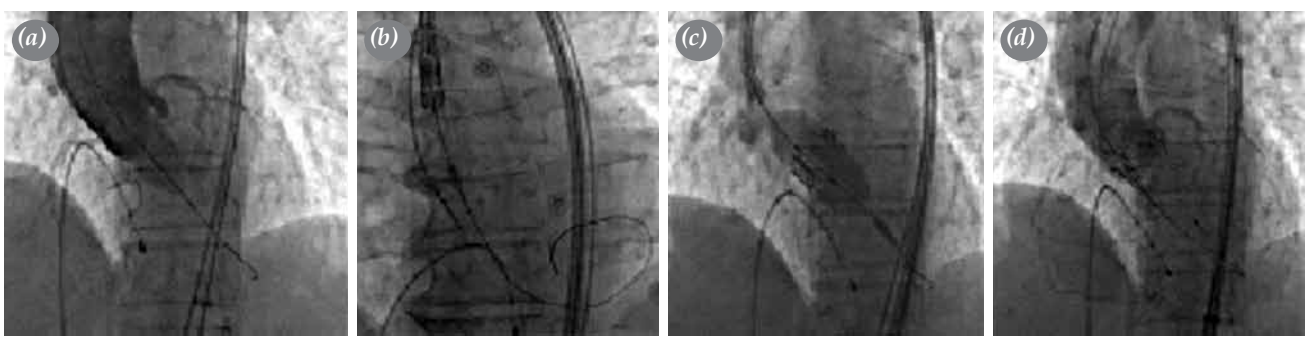

Figure 1. Fluoroscopic images during transcatheter aortic valve (Edwards SAPIEN) implantation; **(a)** Balloon valvuloplasty. **(b)** Advancement of the valve system in the aorta. **(c)** Valve deployment in the aortic position. **(d)** Fluoroscopic aspect of the valve after deployment.

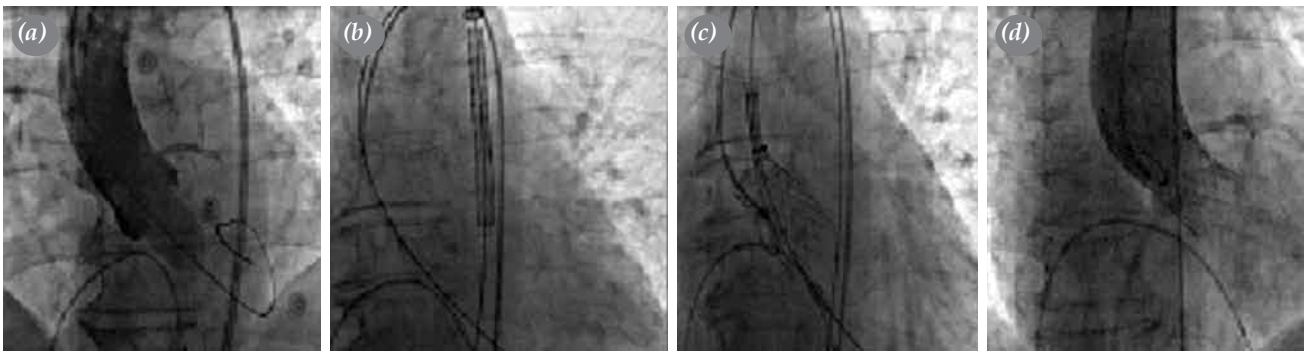

Figure 2. Fluoroscopic images during transcatheter aortic valve (CoreValve) implantation; **(a)** Balloon valvuloplasty. **(b)** Advancement of the valve system in the aorta. **(c)** Valve deployment in the aortic position. **(d)** Fluoroscopic aspect of the valve after deployment.

Statistical analysis

Statistical analysis was performed using the Statistical Package for the Social Sciences (SPSS) version 16.0 for Windows (SPSS Inc, Chicago, Illinois, USA). Data was expressed as mean ± standard deviation (SD) for continuous variables and as numbers with corresponding percentages for categorical variables. The Mann-Whitney U test was used to compare continuous variables, and Fisher's exact test was used to compare categorical variables. The paired Student's t-test was used to compare the pre- and post-procedural results. A *p* value of less than 0.05 was considered to be significant.

RESULTS

The baseline demographic characteristics of the patients are summarized in Table 2. Compared with the patients in the Edwards SAPIEN group, those in the CoreValve group had a higher mean NHYA class. The other baseline characteristics were similar between the two groups.

The clinical characteristics of the patients are presented in Table 3. The overall rates of coronary artery disease (71.4%), pulmonary hypertension (60%), and chronic pulmonary disease (65.7%) were high.

The procedural data is presented in Table 4. All devices were properly positioned, and the valves were found to be properly functioning on post-procedural angiographic and echocardiographic evaluations. The technical procedural success rate was 97%. The procedure was accomplished under general anesthesia in 21 patients and under mild sedation in 14 patients. Access was gained by a surgical cutdown in 25 patients, and a percutaneous closure device (Prostar XL, Abbott Vascular, Redwood City, Calif) was used in 10 patients. The fluoroscopy times and amounts of contrast material used were similar for the two valve types.

Changes in hemodynamic and clinical parameters are summarized in Table 5. At the one-month echocardiographic follow-up, both aortic valve area and left ventricular ejection fraction had significantly increased, but there were significant decreases in the transvalvular (peak systolic and mean) gradients. At the three-month follow-up, the overall mean NYHA functional class score had decreased significantly.

Table 2. Baseline characteristics of the patients (n=35)

	All patients (n=35)			Edwards SAPIEN (n=27)			CoreValve (n=8)			
	n	%	Mean±SD	n	%	Mean±SD	n	%	Mean±SD	*p*
Female (%)	19	54.3		15	55.6		4	50		0.782
Age			77.4±6.9			78.2±5.6			74.6±10.2	0.814
Weight (kg)			72.3±13.2			71.7±13.3			74.4±13.2	0.969
Body mass index (kg/m^2)			27.5±5.3			26.9±4.9			29.5±6.4	0.326
NYHA class			3.5±0.5			3.4±0.5			3.9±0.4	0.022
Ejection fraction (%)			50.1±11.4			51.1±9.8			46.9±16.0	0.747
Logistic EuroSCORE (%)			26.0±9.9			25.8±10.5			26.8±7.8	0.814
STS score (%)			17.1±5.7			17.0±6.4			17.2±2.4	0.969
Follow-up (months)			8.9±5.2			7.8±4.7			12.4±5.4	0.028

SD: Standard deviation; EuroSCORE: European System for Cardiac Operative Risk Evaluation; STS: The society of thoracic surgeons; NYHA: New York Heart Association.

Table 3. Clinical characteristics of the patients (n=35)

	n	%
Coronary artery disease	25	71.4
Neurological dysfunction	2	5.7
Diabetes mellitus	11	31.4
Pulmonary hypertension	21	60
Chronic pulmonary disease	23	65.7
Chronic renal failure	1	2.9
Peripheral vascular disease	17	48.6
Previous cardiac surgery (ACBG)	11	31.4
Previous valve surgery (MVR)	1	2.9
Atrial fibrillation	9	25.7
Mitral regurgitation (>+2)	7	20
Left ventricular ejection fraction %<40	4	11.4

ACBG: Aortocoronary bypass graft; MVR: Mitral valve replacement.

Complications associated with the procedure are summarized in Table 6. The procedural mortality rate was 2.9%. Permanent pacemaker implantation was required in four patients (three CoreValve; one Edwards SAPIEN) due to atrioventricular conduction abnormalities. In one patient in the CoreValve group, implantation was unsuccessful due to valve dislodgment in the ascending aorta. Peripheral arterial injuries occurred in three patients. Pericardial effusion and tamponade occurred in a female patient four hours after the implantation of an Edwards SAPIEN valve while coronary artery occlusion occurred in two patients in the Edwards SAPIEN group. Four patients (11.4%) had no post-procedural paravalvular insufficiency, whereas 27 patients had grade 1+, three patients had grade 2+, and one patient had grade 3+ insufficiency (77.1%, 8.6%, and 2.9%, respectively). There were no significant changes in paravalvular insufficiency during the follow-up.

In-hospital and follow-up events: Four cardiac deaths (11.4%) occurred during the 30 days of follow-up. One patient in the CoreValve group died during the procedure, and sudden cardiac arrest occurred in another patient four days after the procedure. Cardiac tamponade developed in one patient, despite pericardiosynthesis, and the hemodynamics of the patient worsened due to severe kyphoscoliosis and lung problems which resulted in mortality three days after the procedure. Stroke developed in one patient, and she died three days after the procedure. In total, over a mean period of 8.9 months of follow-up (range 0-17 months), nine deaths occurred due to non-cardiac (n=3) and cardiovascular (n=6) causes. Of these, three were in the CoreValve group, and six were in the Edwards SAPIEN group.

DISCUSSION

In our country, the first successful TAVI was reported by Yücel et al.[9] Afterwards, Dagdelen et al.[10] presented their first follow-up data. In the present study, the patients who underwent TAVI were at high risk for surgical procedures. However, the success rate was high, the complication rate was low, and short- and mid-term clinical and hemodynamic results were favorable. The functional capacities of the patients increased, and there were significant increases in left ventricular ejection fractions at the one-month follow-up.

Table 4. Procedural data of the patients (n=35)

	Edwards SAPIEN (n=27)			CoreValve (n=8)		
	n	%	Mean±SD	n	%	Mean±SD
Valve size (mm)						
23 mm	13	37.1				
26 mm	14	40		4	11.4	
29 mm				4	11.4	
Approach						
Transfemoral	26	74.3		7	20	
Transapical	1	2.9				
Subclavian				1	2.9	
Arterial hemostasis						
Percutaneous	7	20		3	8.6	
Surgical	20	57.1		5	14.3	
Anesthesia						
General	15	42.9		6	17.1	
Local	12	34.3		2	5.7	
Fluoroscopy time (min)			22.9±5.5			23.3±3.9
Contrast (ml)			212.4±48.0			240±41.5

SD: Standard deviation

Table 5. The hemodynamic and clinical parameters prior to and subsequent to TAVI

	Preoperative procedure	Postoperative procedure	*p*
	Mean±SD	Mean±SD	
Aortic valve area (cm^2)	0.6±0.1	1.9±0.2	<0.001
Ejection fraction (%)	50.1±11.4	52.5 ±10.4	<0.001
Gradient peak systolic (mmHg)	85.9±14.5	20.2 ±5.9	<0.001
Gradient mean (mmHg)	53.3±8.0	9.8±2.7	<0.001
NYHA functional class	3.5±0.5	1.40±0.56	<0.001

NYHA: New York Heart Association.

Transcatheter aortic valve implantation has emerged as an alternative to surgical aortic valve replacement for symptomatic patients with severe aortic stenosis and very high or prohibitive operative risk. The mortality and morbidity rates for the procedure are lower than what is normally expected from the EuroSCORE and STS scores. In addition, the aortic valve area increases and the functional capacities of the patients improve dramatically. The selection of the TAVI valve and appropriate approach are based on the size, calcification, and tortuosity of the femoral and iliac arteries, calcification of the aortic arch, and the size of the annulus. For patients with an unsuitable femoral access, alternatives include the apical, subclavian,[11] open iliac, or ascending aorta[12] approaches, or reconstruction of the iliofemoral axis with stenting or grafting. We used the transfemoral approach in 33 patients. Of these, one patient with a bilateral aortoiliac vascular graft underwent successful transfemoral TAVI through the left femoral artery and the left graft. Another patient who had bilateral stenosis of the iliac artery underwent transfemoral TAVI and simultaneous percutaneous balloon dilatation. Transfemoral indications for TAVI have been increasing with the development and use of new-generation valves and delivery systems.

Although TAVI has proven to be a less invasive treatment for high-risk patients with aortic stenosis, it may be associated with potentially severe complications. After TAVI, significant paravalvular leakage can occur,[13] which may be related to an undersized prosthesis, malpositioning of the device, or the presence of heavily calcified aortic cusps of the native valve or bicuspid valve.[14] This complication was more frequent with the first-generation valves,[15] as the new-generation systems are less likely to be associated with moderate-to-severe paravalvular leaks. Mild-to-moderate paravalvular leakage, on the other hand, is usually tolerated well. In three cases, (2+) paravalvular leaks were observed. One patient with bicuspid aortic stenosis developed (3+) paravalvular leakage, which decreased slightly during the first month and had no increase later on. Having a self-expandability feature, the CoreValve may be a better option in patients with bicuspid aortic stenosis since this increases compliance with different aortic dimensions. In addition, the upper part of the valve is further expanded, providing better fixation to the ascending aorta. We preferred the CoreValve in the patient with bicuspid aortic stenosis in order to provide better support to the aortic root.

Table 6. Procedural complications of TAVI (n= 35)

	n	%
Procedural mortality	1	2.9
Permanent pacemaker implantation	4	11.4
Paravalvular aortic regurgitation (>+2)	1	2.9
Renal failure requiring dialysis	2	5.7
Major bleeding	1	2.9
Coronary obstruction	2	5.7
Stroke	1	2.9
Vascular complications (access-side)	3	8.6

Perforation or dissection of the iliofemoral arteries might occur due to damage during sheath insertion. Dissection of the ascending or descending aorta may also occur due to catheter trauma or as a complication of aortic valvuloplasty.[16] Three patients had femoral artery injuries that required surgical repair. This occurred during the insertion of the percutaneous closure device in two patients and during advancement of the delivery system in one. There should be no calcification in the entrance area during placement of the percutaneous closure device, and calcification in one patient might have caused them to be predisposed to arterial injury.

Embolic stroke may occur due to aortic wall injury during the procedure. Other potential causes include a calcific embolism from the aortic valve, thromboembolism from a catheter, prolonged hypotension, and dissection of the arch vessels. Stroke rates with current devices range from 0 to 10%.[17,18] One of our patients experienced stroke, most probably due to excessively dense valvular calcification. If the annulus is narrower, the patient will spend a longer time under fluoroscopy and with the contrast medium.

Right heart perforation is also possible during transvenous pacemaker implantation. The incidence of tamponade after TAVI varies from 0 to 7%.[6] Even though pericardiocentesis is adequate for treatment, a thoracotomy may be required. Pericardial effusion and tamponade developed in one patient four hours after the procedure. This complication was attributed to temporary pacemaker placement, and pericardiocentesis was sufficient for treatment. We now apply temporary pacing with a lead balloon in our cases and have had no complications.

Blockage of the coronary ostium by a native calcified valve has been reported.[19,20] In one of our female patients, left main coronary artery occlusion was caused by a plaque that shifted from the native valve during the implantation of the Edwards SAPIEN valve. This complication was immediately noted and dealt with by stenting. The risk for coronary occlusion is low, but once it occurs, it is difficult to assess. It is most likely associated with the bulkiness of the native leaflets, height of the coronary ostia, and dimensions of the sinus of Valsalva.

Atrioventricular block, a known complication of surgical aortic valve replacement, has a reported incidence of up to 8.2%.[21] In an initial report on TAVI-induced heart block, pacemaker implantation was required in 7% and 18% after the use of current balloon-expandable and self-expanding devices, respectively.[22,23] This may be due to the fact that the CoreValve extends further towards the septum, which may cause greater pressure on conduction of the ventricular septal pathways. In our study, permanent pacemaker placement was needed in one patient (3.7%) in the Edwards SAPIEN valve group and in three patients (37.5%) in the CoreValve group.

Compared to the initial practices, procedural success rates have risen with an increased learning curve and with the use of new-generation valves. No significant differences have been reported between the CoreValve and Edwards SAPIEN valve systems in terms of operational success, with 30-day mortality rates of 12% and 15%, respectively.[24,25] Considering the anticipated high risk as calculated by the EuroSCORE, early mortality was acceptably low and was strongly associated with the occurrence of procedural complications. Late mortality occurred from 30 days to one year after TAVI, primarily due to post-procedural paravalvular aortic regurgitation of ≥+2 and non-valve-related comorbidities, such as cerebrovascular disease, chronic kidney disease, and heart failure. Among 35 patients treated in our center, the 30-day mortality rate was 11.4%, and the overall mortality rate was 25.7% over a median period of nine months. The logistic EuroSCOREs of our patients were similar to those that have been previously reported, whereas their STS scores were higher.[26,27] The latter may be due to the presentation of our patients with more fragility and comorbidities.

Limitations of the study: As this is a single-center study involving the use of a novel procedure in our country, the numbers of patients in both groups were limited, especially in the CoreValve device group, and may not be sufficient to compare the results of the two different valve types. However, the results of both groups were favorable. Other limitations in our study include the short follow-up periods (one and two months) for two patients and the provision of follow-up echocardiographic and laboratory data for some patients from other centers due to diverse living locations.

In conclusion, transcatheter aortic valve implantation is a safe and reliable technique for patients with severe aortic stenosis who are at high risk for surgery. Our single-center procedural success and early- and mid-term follow-up data are promising for this patient group, and the data is in line with previous studies.

The procedural success will increase with new-generation delivery systems, and indications will expand as this treatment becomes less costly.

Declaration of conflicting interests

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